Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

31 July 2014

English only

2014 Meeting
Geneva, 1-5 December 2014

Biological Weapons Convention
Meeting of Experts
Geneva, 4-8 August 2014
Item 6 of the provisional agenda
Standing agenda item: review of developments in the field of science and technology related to the Convention

The United States of America Government oversight of life sciences dual use research of concern

Submitted by the United States of America

I. Background

1. Despite its value and benefits, certain types of life sciences research, conducted for important and legitimate purposes, can have the potential to generate knowledge, information, products, or technologies that, in the wrong hands, could be misapplied for harmful purposes. Such research is characterized as "dual use" research. The international community has recognized the need for balanced, responsible policies to manage dual use risks without impeding the societal benefits derived from such research.

2. As a result, several entities have fostered what has become an international dialogue regarding dual use oversight of the life sciences, including the World Health Organization (WHO)[1], Royal Netherlands Academy of Arts and Sciences[2], German Ethics Council[3], and the U.S.A. Government[4], including through its National Science Advisory Board for

[1] Meeting on "Dual Use Research of Concern: Current Issues and Innovative Solutions," World Health Organization, 26-28 February 2013, Geneva, Switzerland. Report available at http://www.who.int/csr/durc/durc_feb2013_full_mtg_report.pdf?ua=1.

[2] *Improving Biosecurity: Assessment of dual-use research*, Royal Netherlands Academy of Arts and Sciences, December 2013, ISBN 978-90-6984-678-1. Report available at http://www.knaw.nl/en/news/publications/improving-biosecurity-1.

[3] *Opinion: Biosecurity – freedom and responsibility of research*, German Ethics Council 7 May 2014. Summary and recommendations available at http://www.ethikrat.org/welcome?set_language=en.

[4] http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-of-concern/international-engagement.

Biosecurity. A dynamic dialogue continues within the Biological Weapons Convention (BWC) itself, as reflected in presentations[5], side events[6], and statements by several States Parties[7].

3. In 2012, the U.S.A. Government issued the Policy for Oversight of Life Sciences Dual Use Research of Concern[8], requiring U.S. federal departments and agencies that fund life sciences research to identify and manage the risks associated with dual use research of concern (DURC). DURC is a small subset of dual use research, defined by the U.S.A. Government as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." The 2012 U.S.A. Government DURC policy seeks to mitigate risks created by DURC by establishing regular federal review of U.S.A. Government-funded or -conducted research involving specific high-consequence pathogens and toxins. The aim of this federal oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies generated by such research.

II. A New U.S.A. Government Policy for Institutional Oversight of Life Sciences DURC

4. In recognition of the pivotal role of research institutions and their scientists in identifying and managing DURC, the U.S.A. Government will release a second policy that expands DURC oversight to research institutions receiving U.S. federal funding. The forthcoming Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern[9] (DURC institutional policy) will articulate the practices and procedures required to ensure that DURC is identified at the institutional level and that risk mitigation measures are implemented as necessary. The institutional DURC policy will complement the 2012 DURC policy by establishing institutional review processes and oversight requirements for institutions receiving federal funding for life sciences research. In developing the institutional DURC policy the U.S.A. Government received input from the research community, academia, scientific associations, and other members of the American public to develop a policy that promotes open sharing of research results while seeking to minimize their potential misuse. Together, the two U.S.A. Government DURC oversight policies

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[5] Plenary presentations to the 2013 BWC Meeting of States Parties (MSP) by the Netherlands (*Biosecurity in the Netherlands*) and to the 2013 BWC Meeting of Experts (MXP) by WHO (*WHO 2013 Informal Consultation on Dual-Use Research of Concern*).

[6] Side events at the 2013 MSP by the Royal Netherlands Academy of Arts & Sciences (*Improving Biosecurity - Assessment of Dual Use Research*); at the 2013 MXP by Indonesian Academy of Sciences and Royal Netherlands Academy of Arts and Sciences (*Dealing with Dual Use Research of Concern*); at the 2012 MSP by Canada (*Awareness of the Dual-Use Challenges into Biosafety and Biosecurity Training and Education for Life Scientists*); and at the 2012 MXP by the Netherlands and the U.S. (*Dual Use Research of Concern: The H5N1 Controversy and its Implications for Science Governance*).

[7] Opening statements to the 2013 MXP by the Russian Federation (page 2), Malaysia (page 2), India (page 1) and Switzerland (page 5); S&T plenary statement to the 2013 MXP by Iran on behalf of the Non-Aligned Movement and Other States Parties; National Implementation plenary statement to the 2013 MXP by Switzerland; and opening statements to the 2012 MSP by Pakistan (page 3), India (page 3), U.S. (page 2), and Chile (page 1).

[8] http://www.phe.gov/s3/dualuse/documents/us-policy-durc-032812.pdf.

[9] http://www.phe.gov/s3/dualuse.

work to engage life sciences research institutions and federal funding agencies in a shared responsibility to address the risk that knowledge, information, products, or technologies generated from life sciences research could be used for harm. In addition, the two U.S.A. Government DURC oversight policies together emphasize a culture of responsibility by reminding all involved parties of the shared interest in upholding the integrity of science and in preventing its misuse.

5. Research that is categorized as DURC is often vitally important to science, public health and agriculture, and its findings often contribute meaningfully to the broader base of knowledge that advances scientific and public health objectives. Therefore, it is important to emphasize that a determination of research as being in the category of DURC does not suggest that the research should not be conducted, nor is it the intention of the institutional DURC policy to discourage its pursuit. Rather, a DURC determination indicates a need for greater oversight, and for a collaborative and informed assessment of the potential benefits and risks of the research. In recognition of this, both U.S.A. Government DURC policies note that oversight of DURC, including implementation of risk mitigation measures, should minimize, to the extent possible, adverse impact on legitimate research; should be commensurate with the risk; should include flexible approaches that leverage existing review processes; and should endeavor to preserve and foster the benefits of research.

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The United States of America government policy for oversight of life sciences dual use research of concern (DURC)

Submitted by the United States of America

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Item 7 of the provisional agenda
Standing agenda item: strengthening national implementation

Strengthening national implementation: elements of an effective national export control system

I. Introduction

1. The 2012 Biological Weapons Convention (BWC) Meeting of States Parties "reiterated calls for appropriate measures, including effective national export controls, by all States Parties to implement Article III, in order to ensure that direct and indirect transfers relevant to the Convention, to any recipient whatsoever, are authorized only when the intended use is for purposes not prohibited under the Convention." Well-designed and -implemented national controls are not only critical to fulfilling the obligations of Article III, they are also essential to implementing United Nations Security Council Resolution 1540, which decided that all UN Member States shall:

> *Establish, develop, review and maintain appropriate effective national export and trans-shipment controls over [nuclear, chemical, or biological weapons, means of delivery, and related materials], including appropriate laws and regulations to control export, transit, trans-shipment and re-export and controls on providing funds and services related to such export and trans-shipment such as financing and transporting that would contribute to proliferation, as well as establishing end-user controls; and establishing and enforcing appropriate criminal or civil penalties for violations of such export control laws and regulations.*

2. Appropriately designed and implemented controls are fully consistent with the requirements of Article X of the BWC and limited to non-proliferation measures, neither favouring the commercial development of industries nor hindering legitimate economic development of other countries. In practice, controls should affect only sales in the very few cases where there is evidence of an interest in, or a risk of diversion to, developing or maintaining a chemical or biological weapons (CBW) capacity or terrorism.

3. While States Parties have strongly endorsed the need for effective national export controls, and many delegations have briefed on their national control systems, States Parties

have not, to date, explored the question of what constitutes an "effective" system. While national systems may vary in many details, there is a series of attributes or elements common to effective control systems. Focused discussion by States Parties could therefore promote common understanding and effective action to strengthen national control systems, and thus implementation of the Convention.

II. Elements of an effective export control system

4. The purpose of biological weapons (BW)-related export controls is to limit the risks of proliferation and terrorism involving biological weapons by requiring government permission for and oversight of transfers of tangible and intangible goods and technologies that could contribute to the development, production, or stockpiling of such weapons, consistent with Article III, typically through a licensing process. Such requirements should not be intended to impede legitimate trade or peaceful international cooperation that could not contribute to CBW activities or terrorism. To the contrary, by providing enhanced confidence that such exchange will be used for exclusively peaceful purposes, export controls serve to reduce levels of concern and enhance international exchange of life-science-related knowledge, equipment, and materials.

5. Effective systems for processing requests for government permission for transfers of tangible and intangible goods and technologies generally have six key components:

(a) Laws and regulations that are sufficiently clear and comprehensive, and that establish necessary legal authorities and appropriate penalties for violations;

(b) Clearly established procedures and mechanisms for investigation and enforcement;

(c) A list of items subject to control that is clearly written and focused on the materials and technologies needed to develop, produce, or stockpile biological weapons, such as the list set out by the United Nations in S/2006/853 ("List of chemical and biological items, materials, equipment, goods and technologies related to other weapons of mass destruction programmes, as approved by the Committee pursuant to paragraph 8(a)(ii) of resolution 1718 (2006)").

(d) Controls on technology directly associated with listed items, including transfers of such technology in intangible form and via intangible means;

(e) A "catch-all" provision that obligates exporters to seek government permission for an export if they have reason, either from government communication or in the course of business, to suspect the export is intended to contribute to the development, production, or stockpiling of biological weapons; and

(f) Regular outreach to life science researchers and the biotechnology industry concerning these requirements to ensure awareness and compliance.

III. Factors for consideration in making a licensing decision

6. It is important to bear in mind that the vast majority of global trade in dual-use items and biotechnology is legitimate, so government permission to export is only seldom denied under these regulations. However, since those seeking to acquire materials for biological weapons purposes are unlikely to declare their intentions, the stated peaceful use of a proposed transfer, and the stated end user, cannot automatically be taken at face value. Officials evaluating requests for government permission to export BW-relevant items should therefore take into account indicators of proliferation risk, such as:

(a) Information about proliferation and terrorism involving biological weapons, including any proliferation- or terrorism-related activity, or information about the involvement of any of the parties to the transaction in clandestine or illegal procurement activities;

(b) The significance of the transfer in terms of: (1) the appropriateness of the stated end-use (e.g. , consistency of the item with the stated end-use, and the consistency of both with the stated end-user), including any relevant assurances submitted by the recipient state or end-user, and (2) the potential development of biological weapons;

(c) The assessment of the end-use of the transfer, including whether a transfer has been previously denied to the end-user, whether the end-user has diverted for unauthorized purposes any transfer previously authorized, and, to the extent possible, whether the end-user is capable of securely handling and storing the item transferred;

(d) The role of distributors, brokers, or other intermediaries in the transfer, including, where appropriate, their ability to provide authenticated documents specifying the importer and ultimate end-user of the items to be transferred, as well as the credibility of assurances that the items will reach their stated end-users;

(e) The capabilities and objectives of the chemical and biological activities of the recipient state and the extent and effectiveness of the export control system of the recipient state, as well as any intermediate states;

(f) The applicability of relevant multilateral agreements, including the BWC.

IV. Conclusion

7. National export control systems that incorporate the six key elements described above are increasingly widespread among BWC States Parties – but unfortunately not yet ubiquitous. Many states' systems possess some of these characteristics, but not others (for example, a state may have high-quality laws and regulations, but lack enforcement capacity, or have enforcement capacity but be hampered by insufficient legal authorities). BWC States Parties could make a substantial contribution to strengthening implementation of the BWC and to international security by adoption a clear "common understanding" that these six components are core elements of the effective national export controls called for by the 2012 Meeting of States Parties.

8. States Parties could take a further important step toward effective action by agreeing upon a "common understanding" that the six indicators of proliferation risk cited above, which are widely recognized as international best practice, should be taken into account by States Parties in making licensing decisions for the export of BW-relevant items.

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Item 7 of the provisional agenda
Standing agenda item: strengthening national implementation

Strengthening national implementation: Elements of an effective national export control system

Submitted by the United States of America

First page

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Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Item 7 of the provisional agenda
Standing agenda item: strengthening national implementation

Strengthening national implementation: elements of an effective national export control system

Submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain and the United States of America

I. Introduction

1. The 2012 BWC Meeting of States Parties "reiterated calls for appropriate measures, including effective national export controls, by all States Parties to implement Article III, in order to ensure that direct and indirect transfers relevant to the Convention, to any recipient whatsoever, are authorized only when the intended use is for purposes not prohibited under the Convention." Well-designed and -implemented national controls are not only critical to fulfilling the obligations of Article III, they are also essential to implementing United Nations Security Council Resolution 1540, which decided that all UN Member States shall:

> *Establish, develop, review and maintain appropriate effective national export and trans-shipment controls over [nuclear, chemical, or biological weapons, means of delivery, and related materials], including appropriate laws and regulations to control export, transit, trans-shipment and re-export and controls on providing funds and services related to such export and trans-shipment such as financing and transporting that would contribute to proliferation, as well as establishing end-user controls; and establishing and enforcing appropriate criminal or civil penalties for violations of such export control laws and regulations.*

2. Appropriately designed and implemented controls are fully consistent with the requirements of Article X of the BWC and limited to non-proliferation measures, neither favoring the commercial development of industries nor hindering legitimate economic development of other countries. In practice, controls should affect only sales in the very

few cases where there is an unacceptable risk of diversion to, developing or maintaining a CBW capacity or terrorism.

3. While States Parties have strongly endorsed the need for effective national export controls, and many delegations have briefed on their national control systems, States Parties have not, to date, explored the question of what constitutes an "effective" system. While national systems may vary in many details, there are a series of attributes or elements common to effective control systems. Focused discussion by States Parties could therefore promote common understanding and effective action to strengthen national control systems, and thus implementation of the Convention.

II. Elements of an effective export control system

4. The purpose of BW-related export controls is to limit the risks of proliferation and terrorism involving biological weapons by requiring government permission for and oversight of transfers of tangible and intangible goods and technologies that could contribute to the development, production, or stockpiling of such weapons, consistent with Article III, typically through a licensing process. Such requirements should not be intended to impede legitimate trade or peaceful international cooperation that could not contribute to CBW activities or terrorism. To the contrary, by providing enhanced confidence that such exchange will be used for exclusively peaceful purposes, export controls serve to reduce levels of concern and enhance international exchange of life-science-related knowledge, equipment, and materials.

5. Effective systems for processing requests for government permission for transfers of tangible and intangible goods and technologies generally have six key components:

(a) Laws and regulations that are sufficiently clear and comprehensive, and that establish necessary legal authorities and appropriate penalties for violations;

(b) Clearly established procedures and mechanisms for appealing licensing decisions, investigating possible violations, and enforcing rules and penalties;

(c) A list of items subject to control that is clearly written and focused on the materials and technologies needed to develop, produce, or stockpile biological weapons, such as the list set out by the United Nations in S/2006/853 ("List of chemical and biological items, materials, equipment, goods and technologies related to other weapons of mass destruction programmes, as approved by the Committee pursuant to paragraph 8(a)(ii) of resolution 1718 (2006)"). Such lists should be regularly reviewed and updated as necessary.

(d) Controls on technology directly associated with listed items, including transfers of such technology in intangible form and via intangible means;

(e) A "catch-all" provision that obligates exporters to seek government permission for an export if they have reason, either from government communication or in the course of business, to suspect the export is intended to contribute to the development, production, or stockpiling of biological weapons; and

(f) Regular outreach to life science researchers and the biotechnology industry concerning these requirements to ensure awareness and compliance, e.g. through publication of regulatory handbooks and other guidance and resource documents, making such materials available online, and arranging or taking part in seminars and workshops to inform industry and academia.

III. Factors for consideration in making a licensing decision

6. It is important to bear in mind that the vast majority of global trade in dual-use items and biotechnology is legitimate, so government permission to export is only seldom denied under these regulations. However, since those seeking to acquire materials for biological weapons purposes are unlikely to declare their intentions, the stated peaceful use of a proposed transfer, and the stated end user, cannot automatically be taken at face value. Officials evaluating requests for government permission to export BW-relevant items should therefore take into account indicators of proliferation risk, such as:

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(b) The significance of the transfer in terms of (1) the appropriateness of the stated end-use (e.g., consistency of the item with the stated end-use, and the consistency of both with the stated end-user), including any relevant assurances submitted by the recipient state or end-user, (2) the other possible civil and military applications of the item, and (3) the potential development of biological weapons

(c) The assessment of the end-use of the transfer, including whether a transfer has been previously denied to the end-user, whether the end-user has diverted for unauthorized purposes any transfer previously authorized, and, to the extent possible, whether the end-user is capable of securely handling and storing the item transferred;

(d) The role of distributors, brokers, or other intermediaries in the transfer, including, where appropriate, their ability to provide authenticated documents specifying the importer and ultimate end-user of the items to be transferred, as well as the credibility of assurances that the items will reach their stated end-users;

(e) The capabilities and objectives of the chemical and biological activities of the recipient state and the extent and effectiveness of the export control system of the recipient state, as well as any intermediate states;

(f) The applicability of relevant multilateral agreements or sanctions, including the BWC.

IV. Conclusion

7. National export control systems that incorporate the six key elements described above are increasingly widespread among BWC States Parties – but unfortunately not yet ubiquitous. Many states' systems possess some of these characteristics, but not others (for example, a state may have high-quality laws and regulations, but lack enforcement capacity, or have enforcement capacity but be hampered by insufficient legal authorities). BWC States Parties could make a substantial contribution to strengthening implementation of the BWC and to international security by adoption a clear "common understanding" that these six components are core elements of the effective national export controls called for by the 2012 Meeting of States Parties.

8. States Parties could take a further important step toward effective action by agreeing upon a "common understanding" that the six indicators of proliferation risk cited above, which are widely recognized as international best practice, should be taken into account by States Parties in making licensing decisions for the export of BW-relevant items.

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Item 8 of the agenda
Biennial item: how to strengthen implementation of Article VII, including consideration of detailed procedures and mechanisms for the provision of assistance and cooperation by States Parties

Article VII – Procedures

Submitted by South Africa

Introduction

1. Article VII of the BTWC requires from States Parties to "provide or support assistance, in accordance with the United Nations Charter, to any State Party which so requests, if the Security Council decides that such Party has been exposed to danger as a result of a violation of the Convention."

2. There are two issues of contention with regard to Article VII: the need for a procedure for assistance and the possible relationship between Art VII and Art X. Given the differences of opinion on the latter, this Working Paper focuses exclusively on the procedure for assistance under Article VII.

Procedure for Assistance

3. Under Article VII, the final declaration of the 6th Review Conference states the following: "The Conference notes that State Parties' national preparedness contributes to international capabilities for response, investigation and mitigation of outbreaks of disease, including those due to alleged use of biological or toxin weapons."

4. The 7th Review Conference declared: "The Conference notes that State Parties' national preparedness contributes to international capabilities for response, investigation and mitigation of outbreaks of disease, including those due to alleged use of biological or toxin weapons. The Conference notes that there are differences among States Parties in terms of their level of development, national capabilities and resources, and that these

differences affect national and international capacity to respond effectively to an alleged use of a biological or toxin weapon. The Conference encourages States Parties, in a position to do so, to assist other States Parties, upon request, to build relevant capacity."

5. The Conference further stated: "On the provision of assistance and coordination with relevant organizations upon request by any State Party in the case of alleged use of biological or toxin weapons, States Parties recognize that in this regard health and security issues are interrelated at both the national and international levels. The Conference highlights the importance of pursuing initiatives in this area through effective cooperation and sustainable partnerships. The Conference notes the importance of ensuring that efforts undertaken are effective irrespective of whether a disease outbreak is naturally occurring or deliberately caused, and cover diseases and toxins that could harm humans, animals, plants or the environment. The Conference also recognises that capabilities to detect, quickly and effectively respond to, and recover from, the alleged use of a biological or toxin weapon need to be in place before they are required."

6. At the 6th and 7th Review Conferences, proposals were made that States Parties may need to discuss the detailed procedure for assistance in order to ensure that timely emergency assistance would be provided by States Parties.

7. The 7th Review Conference recognised "that there are challenges to developing effective measures for the provision of assistance and coordination with relevant international organizations to respond to the use of a biological or toxin weapon."

8. It is accepted that it may not be possible to develop and agree on measures for the provision of assistance in accordance with Art VII, however, a set of guidelines to aid a State Party when submitting an application for assistance to the United Nations Security Council may be useful. In this paper guidelines that could be utilised are proposed.

Guidelines for Requesting Assistance

9. Information to be supplied with the Application

(a) Name of the State Party.

(b) Date and place of first reported case. If there was a related event, a description of the event. To the extent possible, the date and time, when the alleged event(s) took place and/or became apparent to the requesting State Party and, if possible, the duration of the alleged event(s).

(c) Severity of the event. Number of cases and the number of fatalities, if any.

(d) Symptoms and signs – diagnosis if possible. Information on the initial treatment and the preliminary results of the treatment of the disease

(e) A description of the area involved.

(f) All available epidemiological information

(g) Actions taken to manage the outbreak.

(h) International organisations already involved in providing assistance.

(i) States already involved in providing assistance.

(j) Indications of why the outbreak is considered to be the result of a biological attack.

(k) Characteristics of the agent involved, if available.

(l) Types and scope of assistance required.

(m) Indication of any investigations conducted or being conducted

10. **Actions**

The application is to be submitted to the UNSG for forwarding to the UNSC as an urgent matter. It can simultaneously be submitted to one of the Depositories as an urgent matter.

Conclusion

11. It is suggested that States Parties consider a set of guidelines to aid a State Party when submitting an application for assistance to the United Nations Security Council.

12. The guidelines provided above could be useful in this regard.

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Item 7 of the agenda
Standing agenda item: strengthening national implementation

A Response to BWC/MSP/2012/WP.11: "We Need to Talk about Compliance"

Submitted by the United States of America

Introduction

1. The United States of America places great importance on compliance with the Biological Weapons Convention. Furthermore, as we have stated previously, maintaining and promoting confidence that parties are abiding by their commitments is essential to **any** treaty. The BWC poses special challenges in this regard. The broad nature of its obligations, the intent-based nature of the Article I prohibition, the inherently dual-use nature and widespread availability of the materials and technology in question, and the potential significance of even small quantities of pathogenic material all combine to render traditional arms control approaches to enhancing assurance ineffectual. The increased significance in recent years of non-state actors as an element of the international biological weapons (BW) threat the Convention seeks to address only exacerbates this problem. As a result, there is no simple "checklist" of specific actions or activities that may be applied to determine that a State Party is complying with all its obligations under the Convention.

2. There are thus no easy answers to the challenge of how to increase confidence in compliance with the BWC. This makes it all the more important for States Parties to exchange views on how they think about compliance and to discuss ways in which they can demonstrate greater transparency, with the aim of reducing doubts or concerns about their actions or intentions and considering options for addressing such concerns should they arise.

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Compliance with the Biological Weapons Convention (BWC)

3. In the view of the United States, each party to a treaty has both the right and the responsibility to make its own determinations about whether or not other Parties are complying with their obligations, and to address any concerns other Parties may have. This is true not only in the context of the BWC, but also in treaties that include a verification regime or other compliance-related mechanisms, which exist to provide additional information to inform such judgments, not to supplant them. It is also important to be mindful that "compliance" is not a one-time event, but a continuous state, and thus judgments about compliance are likewise an ongoing process.

4. While a definitive compliance "checklist" is not possible, it is certainly possible to identify key elements that might be taken into consideration in evaluating compliance. Any such judgment must consider the basic obligations of the Convention. Compliance requires a State Party to **refrain** from certain actions (e.g., developing, stockpiling, or transferring biological weapons) set out in Articles I and III. It also requires a Party to **take** a number of actions, the most critical of which are:

- To eliminate any existing biological weapons or related facilities, in accordance with Art. II.
- To establish appropriate measures to ensure that the Party never transfers biological weapons to any recipient, directly or indirectly, or in any way assists in the acquisition of biological weapons. In general, this is accomplished through efficient and effective national export licensing systems to ensure that materials are only exported for permitted purposes. Given the Convention's intent-based prohibition, flexible "catch-all" provisions are an essential element of such systems.
- To adopt "any necessary measures" to "prohibit and prevent" anyone under a Party's jurisdiction or control from developing, acquiring, or stockpiling biological weapons.

5. While the Convention does not set out more detailed requirements for "any necessary measures," the Final Documents of seven Review Conferences (RevCons) and the Common Understandings reached under three successive Intersessional Work Programs provide considerable guidance. To be effective, laws and regulations should be clear, enforceable, and actively enforced. They should **prohibit** conduct proscribed by the Convention, and provide for meaningful penalties to deter such action, but they should also aim to **prevent** such action. Such prevention requires a Party to exercise some mixture of oversight, regulation, and outreach for certain permitted activities in order to guard against misuse. Examples include regulations on biosafety, biosecurity, and oversight on the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat. We agree with the UK, Switzerland,[1] and Japan[2] on the importance of engagement with civil society, particularly the scientific community, to promote awareness and a culture of responsibility and/or provide oversight of research and development (R&D). In addition, the precise scope and nature of activities necessary to ensure compliance may vary from one Party to another. We agree with Switzerland and the UK that a judgment about a Party's compliance with the necessary national implementation measures must take into account the level of its development and be realistic about the implementation burden with which some Parties can cope.

[1] BWC/MSP/2013/MX/WP.12.
[2] BWC/MSP/2013/MX/WP.18.

6. The threat of biological weapons acquisition and use by non-state actors has become increasingly clear and relevant. The United States assesses that it is at greater risk of biological weapons attack by terrorists than by nation states. Accordingly, the importance of Articles III and IV as elements of State Parties' compliance with the Convention is greater than it once was. Thus, our collective thinking about compliance with the BWC and how to demonstrate it must take into account this fundamental shift in the BW threat. In this connection, it is worth noting that all States now have binding obligations under United Nations Security Council Resolution 1540 (2004), which reinforce the Article III and IV commitments of Parties. The obligations are to: (a) "refrain from providing any form of support to non-State actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use biological weapons and their means of delivery;" (b) "adopt and enforce appropriate effective laws which prohibit any non-State actor" from engaging in or attempting to engage in a range of proliferation activities; and (c) "take and enforce effective measures to establish domestic controls," including accounting for, securing and physically protecting related materials in production, use, storage and transport, as well as border and export controls, to prevent non-State actors from exploiting legitimate activities for proliferation purposes.

7. Given the dual-use nature of the relevant knowledge, materials, and equipment and the other factors mentioned above, it is often not possible to reach a definitive conclusion about whether or not another Party is fully complying with its obligations under the Convention, nor is it easy to envision a mechanism that would substantially change this situation. As a result, the question that confronts States Parties is ultimately about the level of confidence we share in the compliance of States Parties, individually and collectively – or, put another way, the level of concern we have about non-compliance. In its paper on this subject,[3] the United Kingdom of Great Britain and Northern Ireland usefully listed a range of activities, attitudes, and behaviors that – while generally neither "proving" nor "disproving" a State Party's compliance – tend to influence confidence concerning its activities and intentions.

Better demonstrating BWC compliance and thereby enhancing assurance for other Parties

8. It is important to enhance assurance, but it is not possible to have absolute certitude about another Party's compliance, especially since the basic prohibitions of the BWC address not only capabilities, but also intent. As the United Kingdom notes, single actions are rarely definitive, though the continued presence of the positive factors included in its paper – some of which have to do with intent – enhances assurances of compliance. Indications of intent, while imperfect, reflect the practical reality that a Party can, through its overall actions and behavior, increase or decrease any apprehension other Parties may have about its compliance.

9. Indeed, confidence in compliance can be increased through greater transparency regarding activities and, in particular, national implementation (where current transparency measures are most notably weak). Means of enhancing transparency include providing and regularly updating information through the existing mechanisms of confidence-building measures (CBMs), the National Implementation Database (NID), and the report of the BWC Implementation Support Unit (ISU) to BWC Review Conferences on compliance, as well as participating in regional efforts to strengthen implementation, such as those that have taken place in the past year in Chile, Malaysia, and Mexico. Relevant reporting to the

[3] BWC/MSP/2013/MX/WP.1.

1540 Committee also helps increase confidence, especially as the submissions (and in most cases the matrices prepared by the Committee) are public documents. Indeed, as suggested in the working paper that we, along with Australia, Canada, France, Germany, Netherlands, and the United Kingdom submitted to the 2013 Meeting of States Parties,[4] many Parties could provide information on national BWC implementation with little additional effort by simply submitting the relevant portion of their national 1540 matrix or any BWC-relevant legislative surveys that may have been conducted.

10. We agree with Switzerland that demonstrating compliance consists not only of Parties communicating that they are in compliance by providing relevant information, but also of others considering the information and providing feedback. For this reason, we believe it would be valuable for Parties to consider **how** such information could be used to enhance assurances of compliance. As we proposed at the Seventh RevCon, we also support BWC Parties taking voluntary steps to increase transparency and build confidence, such as through visits to biodefense facilities like those that the United States has conducted[5] and that Switzerland recently hosted at its Spiez facility.

11. We see the concepts of "peer review," "compliance assessment," and other voluntary transparency measures as opportunities to strengthen national implementation itself and to enhance transparency about that implementation, rather than as approaches to determining a Party's compliance. Finally, participating in and reporting on Article X efforts, including in the ISU's Assistance and Cooperation Database and in Article X reports by Parties, can increase confidence that Parties are cooperating on "the further development and application of scientific discoveries in the field of biology for prevention of disease, or for other peaceful purposes," as they have undertaken to do in that article.

Role for declarations and whether information additional to that in CBMs would enhance assurance of compliance

12. The United States does not see a role for "declarations" in demonstrating compliance, except to the extent that the information provided for CBMs, the NID, and the ISU's report to RevCons on compliance can be defined as falling into that category (and, indeed, the CBM forms **are** referred to as "declarations"). Our analysis is that a legally-binding obligation to disclose a substantial number of sites defined as relevant to the Convention, which is part of many concepts involving declarations, would not meaningfully enhance the ability to evaluate most Parties' compliance. The issue here is, again, the very large number of facilities possessing dual-use materials and technology that could be used for BW purposes and the paucity of reliable indicators of use for a prohibited purpose.

13. With regard to CBMs, as we suggested in 2012 and have reiterated since then, we believe that Parties should consider not only how to increase the number of Parties submitting CBM reports, but also how to make the information they contain more readily accessible and how to make constructive use of it.[6] And as we proposed in a 2013 MSP working paper, efforts toward this end – in addition to creating electronic means of submitting CBMs – might include: (a) a comprehensive anonymous ISU survey of all States Parties to learn of specific impediments to CBM participation; (b) a commitment by Parties to review the survey results and use them to devise effective actions for consideration at the Eighth Review Conference; and (c) the establishment of a CBM

[4] BWC/MSP/2013/WP.4.
[5] BWC/MSP/2012/WP.3.
[6] BWC/MSP/2012/MX/WP.4.

assistance network, to be coordinated by the ISU, which would facilitate voluntary information sharing among ministry officials ranging from the very experienced to those for whom CBM submission is a new responsibility.[7] While we think CBMs might benefit from further streamlining and restructuring and are an appropriate tool for greater transparency about implementation, we find it difficult to assess whether additional information on CBMs would enhance assurance without knowing more about why Parties are not participating in them in larger numbers and not making more use of information provided by others.

Further development of Article V mechanisms, including consideration of mutually agreed visits to sites of compliance concern

14. Article V provides a valuable mechanism for enhancing assurances of compliance. Parties should discuss this article further, with a view to making exercise of it seem less confrontational and to enhancing assurance of compliance. Article V provides considerable flexibility regarding the subject of consultations under it. While not explicitly identified as Article V consultations, many bilateral and multilateral exchanges that take place between and among BWC Parties, including those regarding national implementation, CBMs, and cooperation and assistance, are consistent with its terms and spirit, which are focused on cooperation to resolve questions and address problems regarding implementation of the Convention. Such consultations, whether they have an Article V label or not, can be used to enhance assurance and strengthen the Convention in other ways without necessarily raising a charge of noncompliance.

15. We agree with the United Kingdom that the 1991 Consultation Meeting arrangements for Article V could be revisited for the purpose of finding ways to enhance confidence in compliance. For example, as we proposed at the Seventh Review Conference, it may be valuable to develop illustrative examples of options Parties might employ in addressing doubts and ambiguities during Article V consultations.[8]

16. While it might be possible to develop elements to lend greater structure to the process of raising questions and concerns under Article V, such as timelines for responses, on the whole the flexible nature of Article V is an asset and should be preserved. Consultation and cooperation to address any questions or problems arising with respect to implementation of the Convention or its provisions has a decidedly broad scope, encompassing not only raising specific concerns about a State Party's compliance (whether bilaterally or multilaterally) but also, for example, efforts to develop clearer shared understandings of how to implement Article IV and efforts to assist other Parties with national implementation or making CBM reports.

17. Mutually agreed, voluntarily hosted visits to sites of concern have long been an option that is available to States Parties to address questions or concerns, and may or may not prove useful, depending on the nature of the concern and the behavior of the States Parties involved. The United States believes, however, that it would be counterproductive to develop detailed rules or processes for such visits, as flexibility is critical.

[7] WC/MSP/2013/WP.1.
[8] BWC/CONF.VII/WP.23.

Article VI mechanisms and the role of United Nations Secretary General's Mechanism for Investigation of Alleged Use (UNSGM)

18. The provisions of Article VI have never been utilized, but ample opportunity exists at BWC meetings to discuss them. In the event of an allegation of BW use, the United Nations Secretary-General's Mechanism would, in general, be the most suitable vehicle for clarifying the concern. Such an investigation could be launched at the request of the United Nations Security Council in response to an Article VI complaint, but could also be initiated by the United Nations Secretary-General in response to a request from a BWC State Party or other United Nations member state, in which case the results could inform an Article VI complaint to the Security Council. We support taking reasonable steps to strengthen the United Nations Secretary-General's Mechanism's operational capacity to investigate allegations of BW use, particularly the development of concepts of operations and standard operating procedures.

The potential impact of life sciences advances on enhancing assurance of compliance

19. We agree that the discussion of enhancing assurance should take into account the pros and cons of the potential impact of advances in science and technology. We agree with the United Kingdom that forensic epidemiology can be of great utility in investigating possible violations and that advances in technology, particularly bioforensics, are highly relevant in the support of Article VI investigations. However, our assessment is that some advances (e.g., disposable bioreactors, improved containment and decontamination techniques, and improvements in aerosolization technologies for peaceful purposes) might decrease the ability to reliably detect noncompliance.

Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

5 August 2014

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2014 Meeting
Geneva, 1-5 December 2014

Biological Weapons Convention
Meeting of Experts
Geneva, 4-8 August 2014
Item 7 of the provisional agenda
Standing agenda item: strengthening national implementation

National implementation of the Biological Weapons Convention

Submitted by Australia, Japan, Malaysia, Republic of Korea and Thailand

Overview

1. The overall aim of this working paper is to raise awareness among relevant national officials and experts on different aspects of Biological Weapons Convention (BWC) implementation, and to identify needs and requirements for enhancing regional and national programmes and/or initiatives in support of BWC implementation. Effective implementation of the BWC includes but is not limited to effective national legislation, domestic biosecurity regulations and capabilities and export controls on sensitive materials (in some cases, developed through bilateral and regional cooperative efforts). These measures can all work in a complementary manner to enhance biological security globally, reduce the possibility of BW proliferation, and raise barriers to bioterrorism. These measures can also help to improve detection and response capabilities for natural or deliberate disease outbreaks, and facilitate exchange in the life sciences for peaceful purposes.

2. Through a better understanding of national implementation obligations, states parties have the opportunity to work together, in the intersessional programme and in preparations for the Eight Review Conference in 2016, to advance the cause of building a safer world free of the threat of biological weapons. This would also be an opportunity for States Parties to focus their attention to the effective action mandate, as highlighted by the Chairman of the 2014 Meetings of the BWC, in his letter dated 14 February 2014. This working paper provides several ideas which could be the areas of focus for effective action under the standing agenda item on Strengthening National Implementation.

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Introduction

3. Effective implementation of the BWC helps reduce the risks of the biological sciences and biotechnologies being deliberately or inadvertently misused for malign purposes.

4. The Seventh Review Conference has provided us with a range of materials and tools with which to progress effective implementation of the BWC. This has to be acted upon, through the intersessional programme, domestic action, and cooperation with other States Parties and partners such as WHO, INTERPOL, the scientific community, industry, NGOs and civil society. These efforts have contributed to a growing and important discussion involving a diverse group of States Parties on ways to work collectively to strengthen national implementation of the BWC.

Obligations and undertakings

5. In order to effectively implement the BWC, it is important to have a clear understanding of States Parties' obligations and undertakings under the BWC. States Parties need to recognize the importance of measures to cover:

- legislative and regulatory frameworks including;
- export control regimes;
- biosafety and biosecurity;
- disease surveillance and outbreak response capacity;
- oversight of science;
- educational efforts and awareness raising;
- assistance and protection capacity;
- responding to alleged use;
- exchanges of information; and
- building capacity for peaceful use.

6. Further, States Parties are encouraged to participate in the confidence building measures process, the only existing transparency mechanism of the BWC.

7. National implementation legislation is important as it demonstrates political support for the BWC, and is useful in identifying other implementation requirements such as training and assistance needs to strengthen biosecurity preparedness. This would also encourage investments in the field of biology and, most importantly, prevent biological weapons proliferation.

8. However, for the legislation to be effective, it must be implemented effectively and properly promulgated and enforced. Critical in this process will be awareness-raising among key stakeholders such as parliamentarians, the scientific community, and law enforcement and border control officials.

9. For many States Parties national implementation is challenging, requiring education of, and coordination between different national stakeholders. The importance of making an effort towards a whole-of-government approach to implementation needs to be understood. Some specific suggestions on best practices for raising awareness of the BWC and establishing a national BWC implementation mechanism include:

- establishing a central point of contact and coordination for national implementation of the BWC
- establishing mechanisms for regular communication amongst key stakeholders, for example a regular meeting of an inter-governmental committee
- ensuring regular and timely participation in the confidence building measures process, including by involving all relevant areas of government and related areas
- organising awareness-raising workshops and training for establishing of efficient communication and coordination between national stakeholders, and
- promoting the BWC through related initiatives, such as outreach to industry, education and research sectors, and through the European Union CBRN Centres of Excellence.

10. There could also be value during the BWC intersessional period in identifying and exploring parallels in compliance requirements across different disarmament and non-proliferation treaties and international agreements, to maximise synergies and take advantage of existing or planned measures. For example, a State Party that was considering developing or strengthening its BWC national implementing measures could take practical steps to ensure such measures also complemented and enhanced national efforts to implement the Chemical Weapons Convention and the United Nations Security Council Resolution 1540.

Biorisk management, biosafety and biosecurity

11. National implementation requires a focus on national efforts to establish and apply measures to ensure biological agents are handled in a safe and secure way. The rapid developments in biological sciences make biosafety and biosecurity increasingly important considerations. If there is a limited understanding of the BWC and/or a limited awareness of biosecurity, the potential for deliberate or inadvertent mishandling of biological material, and for the proliferation of biological materials, expertise and technology to individuals or countries of concern, remains and may be exacerbated.

12. Strong political will is needed to ensure effective national implementation of the BWC. A low political will results in the absence of appropriate legislation, administrative measures and a lack of funding, leading to a lack of infrastructure and appropriate training. An additional complication arises from the multi-agency nature of BWC implementation. Therefore, an appropriate agency that can assume ownership and constitute a central authority is required to establish efficient coordination as well as biosafety and biosecurity measures.

13. In our modern world, infectious disease travels quickly. The general public has high expectations for immediate information, transparency, and effective responses to ensure their well-being and to limit the economic impacts of disease outbreaks. Therefore, close collaboration between the BWC community and the global health community is important, as there is a growing need for these communities to work together. In this context, national implementation also requires a focus on compliance with the 2005 International Health Regulations, to ensure States Parties can respond to public health emergencies, bioincidents and allegations on the use of biological weapons. Other initiatives such as the new Global Health Security Agenda initiative are also important, which brings together health security and BW non-proliferation objectives.

14. Therefore, compliance with the International Health Regulations is a key indicator of effective national implementation under the BWC. The International Health Regulations

represent a major step forward in international public health security, providing a framework for the collective international management of epidemics and other public health emergencies while minimizing disruption to travel, trade and economies. The International Health Regulations provide a global legal framework to strengthen national and international systems required for managing disease outbreaks and public health emergencies.

15. The International Health Regulations emphasize the importance of national capacities and requests WHO Member States to develop, strengthen and maintain effective, functional national systems and core capacities for surveillance and response particularly at designated international airports, ports and ground crossings. It is important that all countries implement the International Health Regulations, as the whole region suffers if one country does not have implementation.

16. The International Health Regulations core capacity monitoring framework requires annual completion of a 28-page questionnaire requiring multi-agency involvement and covers areas such as national legislation, coordination, risk communication, and commitment. The questionnaire is voluntary, but the fulfilment of this obligation establishes compliance with the IHRs and supports national level BWC implementation.

17. Preparedness is a key for responding to public health emergencies. We need to know quickly what happened, where it happened, who is affected, and how it happened. As such, the first 24 hours following an incident are critical. The deployment of appropriately trained rapid-response teams, the coordination of multi-agency responses and clear lines of communication to officials and the general public will need oversight by a well-defined chain of command to mitigate the effects of any incident. The use of an integrated IT system may also assist but all of these functions need to be established before any emergency occurs. It is also important to have an approach which takes into account the linkage between the health of humans, animals and the ecosystem, and respond to public health emergencies using a multi-hazard approach.

Capacity building

18. Capacity-building is another key issue that needs to be addressed. While there are many ongoing national programmes, changes in priorities and new developments can provide challenges to the implementation of such efforts. The importance of connectivity through networking, cooperation/collaboration and coordination to promote capacity building cannot be overstated. Such activities are required at the national, sub-regional, regional and international levels.

19. Identifying leaders and champions may help promote drive the implementation of the Convention at the national level. Engagement with civil society and the establishment of public-private partnerships can also play a positive role in building capacity.

20. Capacity-building will also be increased through training and awareness-raising activities. "Train the Trainer" is a useful and efficient method for reaching a wider group of actors/stakeholders (often separated geographically or by language barriers), to facilitate the transfer of knowledge. Local-based training could benefit from support by national and/or regional associations and organisations.

21. Sustainability has to be taken into account when building capacity through developing infrastructure and training activities. Nevertheless, it is important to note that systems of developed countries might not be sustainable in, or suitable for, developing countries, due to differences in values and lack of resources. Sub-regional and regional networks have an important role to play in helping to foster understanding and share

lessons learned. We note the efforts of regional bodies such as ASEAN to work in tandem with Global Partnership projects, including those recently supported by Canada as well as the work done with partners of the ASEAN Regional Forum.

International assistance

22. International assistance is available to support national and regional efforts in building capabilities and capacity to prevent, detect and respond to the outbreak of disease or deliberate use of a biological agent. States Parties are encouraged to share information on their support for, or receipt of, international assistance which includes submitting a national report on implementation of Article X of the BWC.

23. Pursuant to the decision of the 7th Review Conference, the BWC assistance database was established to serve as the primary reference point for international assistance within the framework of the Convention. State Parties could also submit any offers of, and requests for, assistance to the United Nations Security Council 1540 Committee. A summary of these requests for assistance can be found on the 1540 Committee website.

24. Regional programs are also available for capacity building. For example, in the Asia Pacific, the United Nations Regional Disarmament Centre for Peace, Disarmament and Development in Asia and the Pacific is developing a 1540 implementation plan and will in the future also support implementation of the BWC. The Centre is based in Kathmandu, Nepal, and would be able to provide states in the region support and advice where required.

25. The ASEAN Regional Forum has been active in promoting and helping to enhance biosecurity and biosafety, in partnership with the US and Australia, and will continue its engagement. This is important as more attention needs to be paid to developments in biology and the life sciences. It also requires building better coordination and cooperation, both domestically and internationally. The ASEAN Regional Forum has organized a series of workshops, highlighting the importance of enhanced cooperation amongst stakeholders, interagency cooperation and cross-disciplinarily biorisk management, and instilling a culture of responsibility in industry and academic instigations.

26. The European Union is also active in the ASEAN region. The European Union Instrument for Stability, launched in 2007, has the objective of restoring stability in the face of a crisis. This is achieved – in part – by building capacity in times of peace for preparedness and mitigation of CBRN events. There have been a number of initiatives in the South-East Asia and South Asia regions including through the European Union CBRN Centres of Excellence Initiative, under the Instrument for Stability. Activities and projects under this initiative try to join existing initiatives to reinforce national CBRN policies. States that have joined a regional centre are encouraged to establish national teams as cooperation between different agencies is required. These national teams assess needs and develop action plans for strengthening CBRN policies, and coordinate project plans.

27. A regional secretariat for the CBRN Centres of Excellence has been established in Manila, the Philippines, for activities in South-East Asia. The secretariat assists regional States in their efforts, has a coordinating role both for participating States and regional organisations, monitors and evaluates projects, and organizes round table meetings.

Conclusion

28. The aforementioned diverse measures can contribute to effective implementation of the BWC in a mutually complementary manner. They are worth being discussed nationally,

sub-regionally, regionally, and internationally among States Parties with a wide range of partners in order to work collectively for further enhancement of national implementation.